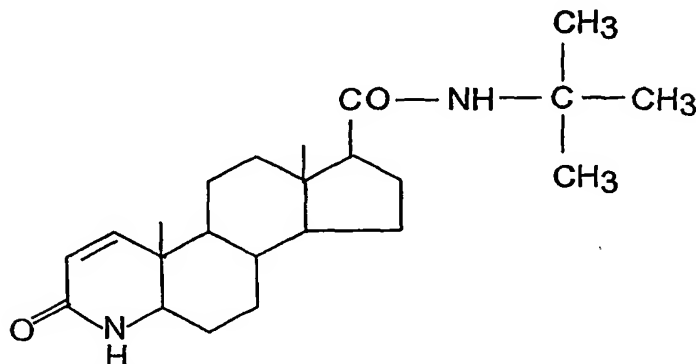


- 10 -

CLAIMS

1. A novel polymorphic Form-III of 17- β -(N-ter. butyl carbamoyl)-4-aza-5- α -androst-1-en-3-one having the formula (I),



which is characterized by the following data:

DSC: exhibits a melting endotherm with a peak temperature of about 262°C and preceded by another minor endotherm at about 245°C and an exotherm at about 253°C.(Fig-1)

XRD (2 θ): 5.32, 10.70, 13.64, 14.96, 15.86, 16.12, 16.56, 17.20, 18.22, 19.60, and 23.04. (Fig-2).

FT-IR (In KBr): 3427, 3233, 2931, 1679, 1600, 1501, 1451 and 820 cm^{-1} .(Fig-3).

2. A process for preparing Form-III of 17- β -(N-ter. butyl carbamoyl)-4-aza-5- α -androst-1-en-3-one, which comprises:

(i) dissolving crude 17- β -(N-ter. butyl carbamoyl)-4-aza-5- α -androst-1-en-3-one in a water immiscible organic solvents,
(ii) saturating the solution with less polar organic solvent,
(iii) concentrating the solution and isolating the Form III of 17- β -(N-ter. butyl carbamoyl)-4-aza-5- α -androst-1-en-3-one by conventional methods.

3. The process as claimed in step (i) of claim 2, wherein the water immiscible organic solvent is selected from halogenated solvent, aromatic hydrocarbon solvent, or organic solvents selected from alkyl acetates.

4. The process as claimed in claim 2, wherein the halogenated solvent is selected from dichloromethane or chloroform.

5. The process as claimed in claim 3, wherein the aromatic hydrocarbon solvent is toluene.

6. The process as claimed in claim 3, wherein the alkyl acetate is selected from ethyl acetate.
7. The process as claimed in step (ii) of claim 2, wherein the less polar organic solvents include solvents selected aliphatic hydrocarbon either straight chain or
5 branched, preferably hexane or heptane or petroleum ether.
8. A process for preparing the Form-III of 17- β -(N-ter. butyl carbamoyl)-4-aza-5- α -androst-1-en-3-one, which comprises,
- (i) dissolving any of the Form-I, Form-II, Form-IV and Form-V of 17- β -(N-ter. butyl carbamoyl)-4-aza-5- α -androst-1-en-3-one in water immiscible organic
10 solvents ,
- (ii) distilling off 60-70% of the solvent,
- (iii) saturating the remaining solution with less polar organic solvents, and
- (iv) concentrating the resultant solution and isolating the Form-III of
15 17- β -(N-ter. butyl carbamoyl)-4-aza-5- α -androst-1-en-3-one by conventional methods.
9. The process as claimed in step (i) of claim 8, wherein the water immiscible organic solvent is selected from halogenated solvent, aromatic hydrocarbon solvent, or organic solvents selected from alkyl acetates.
10. The process as claimed in claim 9, wherein the halogenated solvent is
20 selected from dichloromethane or chloroform.
11. The process as claimed in claim 9, wherein the aromatic hydrocarbon solvent is selected from toluene.
12. The process as claimed in claim 9, wherein the alkyl acetate is selected from ethyl acetate.
- 25 13. The process as claimed in step (iii) of claim 8 wherein the less polar organic solvent include solvents selected aliphatic hydrocarbon either straight chain or branched, preferably hexane or heptane or petroleum ether.
14. Novel polymorphic Form III of 17- β -(N-ter. butyl carbamoyl)-4-aza-5- α -androst-1-en-3-one as described in the claim 1, substantially as herein described.
- 30 15. Process for preparing novel polymorphic Form III of 17- β -(N-ter. butyl carbamoyl)-4-aza-5- α -androst-1-en-3-one as claimed in claims 2-13, substantially as herein described in Examples 2-10.